

TMH/DAG:lam 1/15/04 238673

Attorney Reference Number 6395-57049
Application Number 09/763,397**REMARKS**

Claims 1, 3-6, 10 and 13 are pending in this application. Claims 1 and 13 have been amended to correct antecedent basis as suggested by the Examiner. No new matter is introduced by this amendment, and no new issues are raised. Entry of the amendment after final action is appropriate since the amendment is believed to place the claims in a condition for allowance, and each change has been made at the suggestion of the Examiner.

Upon entry of this amendment claims 1, 3-6, 10 and 13 will be pending in this application. Consideration of this Amendment and entry of the claim amendment herein are requested.

Telephone Interviews:

Applicants thank Examiners Ford and Minnifield for the courtesy of a telephone interview with their representatives, Tanya Harding and Debra Gordon, on January 5, 2004. During the telephone conference, the pending §102(b) and §103(a) rejections were discussed with particular emphasis on the Tine *et al.* (*Infect. Immun.*, 64(9):3833-3844, 1996) reference, which is the primary reference cited in each such rejection.

To facilitate the discussion, Applicants' representatives provided to the Examiners a copy of the diagram attached hereto as Exhibit A. Applicants ask that this diagram be made of record in the file. All parties to the telephone conference agreed that the diagram showed at least some of the differences between Tine *et al.* and the present application. In particular, Applicants explained (and the Examiners agreed) that Tine *et al.* disclose an attenuated virus, which expresses seven separate, full-length (or nearly full length) *Plasmodium falciparum* proteins, wherein each such protein is from only one life stage of the bacteria. Therefore, each *P. falciparum* protein described by Tine *et al.* has epitopes from only one life stage of the *P. falciparum* bacteria. Moreover, Tine *et al.* expressed substantially full-length *P. falciparum* proteins and not discrete, identified immunogenic epitopes. In contrast, the present claims encompass single recombinant proteins comprising particular epitopes from at least two *P. falciparum* life stages in the same protein. This is clearly illustrated in Exhibit A. The Examiners agreed that one or more the distinctions discussed rendered the present claims patentably distinct over Tine *et al.*

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A prior amendment of claim 1 was also questioned by the Examiners. The amendment, which modified the phrase "... the amino acid sequence ..." to "... an amino acid sequence ...," was thought by Applicants' representatives to be advisable for proper antecedent basis. No conclusion was reached on this issue during the January 5, 2004, telephone conference (though it was resolved during a later phone conference, as discussed below). The Examiners further stated that claim 13 should be amended to recite "... the amino acid sequence ...", because antecedent basis for the amino acid sequence was provided in claim 1. Applicants' representatives agreed, and claim 13 is amended herein in conformance with this suggestion.

The Examiners stated that Applicants' representatives should file a response to the final Office action that (i) entered the above-discussed diagram into the case; (ii) reiterated the distinctions discussed during in the interview; and (iii) amended claims 1 and 13 to comply with the discussion of antecedent basis. The Examiners indicated that such a response would place the application and claims in condition for allowance.

Regarding claim 1, Applicants made follow up telephone calls to Examiner Ford on January 9, 12 and 13, 2004. Applicants thank Examiner Ford for briefly calling their representative Tanya M. Harding on January 14, 2004, to indicate that the Examiners prefer that the phrase in claim 1 be changed back to the original language, so that the claim reads "... the amino acid sequence ...". By this Amendment, Applicants have done so.

Applicants believe this Amendment conforms to the helpful suggestions made by the Examiners.

Claim Rejections under 35 U.S.C. §102:

Claims 1, 3, 5, 6, 10 and 13 have been rejected under 35 U.S.C. §102(b) as being allegedly anticipated by Tine *et al.*, *Infect. Immun.*, 64(9):3833-3844, September 1996 ("Tine"). Applicants traverse this rejection for the reasons set forth in the Amendment and Response to Non-Final Office Action, filed June 19, 2003, as further clarified herein.

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As discussed in the January 5, 2004, Examiner interview and as shown schematically in the diagram attached as Exhibit A, Tine *et al.* teach an attenuated virus, which expresses seven separate, full-length (or nearly full length) *Plasmodium falciparum* proteins. Any individual *P. falciparum* protein disclosed by Tine *et al.* is from one life stage of the bacteria. Therefore, each *P. falciparum* protein described by Tine *et al.*, at best, discloses epitopes from only one life stage of the *P. falciparum* bacteria. Moreover, the substantially full-length *P. falciparum* proteins expressed by Tine *et al.* do not teach discrete, identified immunogenic epitopes.

In stark comparison to Tine *et al.*, claim 1 (and, therefore, dependent claims 5, 6, 10, and 13) recites:

1. A single recombinant protein comprising peptides from two or more stages in a life cycle of *Plasmodium falciparum*, wherein each peptide comprises an antigenic epitope comprising the amino acid sequence as set forth as SEQ ID NO: 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, or 25. (emphasis added)

Hence, the present claims encompass single recombinant proteins comprising particular epitopes from at least two *P. falciparum* life stages in the same protein.

With regard to independent claim 3, Tine *et al.* clearly do not teach the amino acid sequence set forth in the present application as SEQ ID NO: 2.

Because Tine *et al.* do not teach each and every element of claim 1 or claim 3, this reference cannot anticipate such claims or claims that depend from either of them (*i.e.*, claims 5, 6, 10 and 13). Thus, Applicants request that this rejection of claims 1, 3, 5, 6, 10 and 13 be withdrawn.

Claim Rejections under 35 U.S.C. §103:

Claims 1, 3-6 and 13 have been rejected under 35 U.S.C. §103 as allegedly being unpatentable over Tine *et al.*, in view of Schmitt *et al.*, *Mol. Biol. Reports*, 18:223-230, 1993 ("Schmitt"). Applicants traverse this rejection for the reasons set forth in the Amendment and

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Response to Non-Final Office Action, filed June 19, 2003, as clarified in the January 5, 2004 telephone interview and reiterated below.

As discussed above, Tine *et al.* do not teach or suggest all of the elements of any of claims 1 or 3-6. Schmitt *et al.* do not teach or suggest the claim elements lacking in Tine *et al.* (e.g., peptides from two or more *P. falciparum* life stages expressed in a single, recombinant protein). Thus, not all the claim limitations are taught or suggested by the cited references and a *prima facie* case of obviousness is not established (MPEP §1504.03). Applicants request that this rejection be withdrawn.

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CONCLUSION

It is respectfully submitted that the present claims are in a condition for allowance.
Applicants request a telephone interview at the telephone number listed below before any further action is taken, in order to deal with any minor remaining issues.

Respectfully submitted,

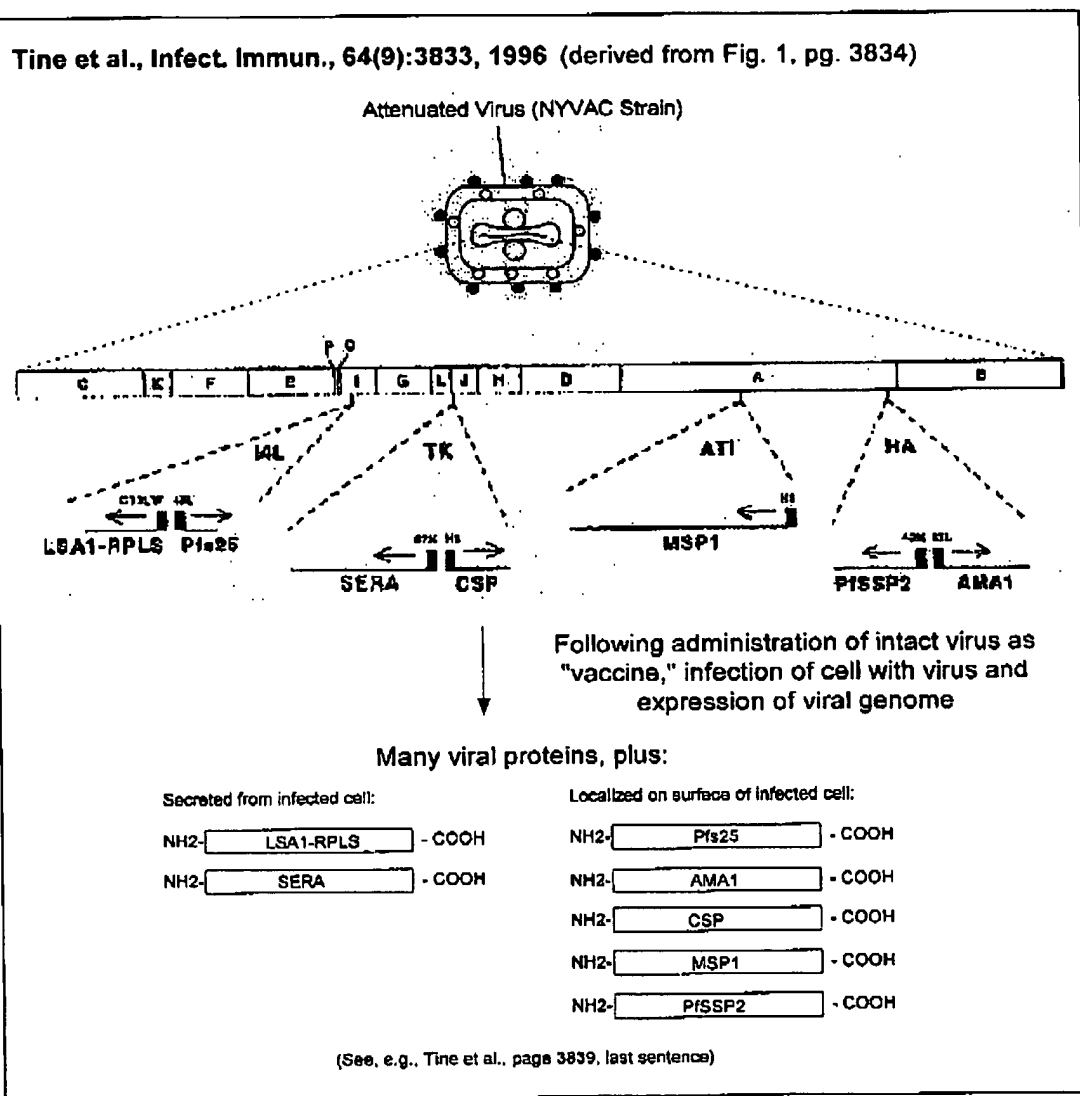
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Application Number 09/763,397**Exhibit A****App. No. 09/763,397**